

REMARKS**Amendments to Claims 4, 5, 4, 43 and 44**

Claims 4, 5, 4, 43 and 44 have been amended to more clearly define that which Applicants regard as the invention. Claim 4 has been amended to specifically claim the nucleic acid set forth in SEQ ID NO:1 and to more clearly describe the detected mutations of SEQ ID NO: 1. As described in the specification at, for example, page 7, lines 23-27, the EPM2B gene (SEQ ID NO:1) is an isolated nucleic acid molecule encoding a protein containing a zinc finger of the RING type in the N-terminal portion and 6 NHL-repeat domains in the C-terminal portion that is associated with Lafora's disease. This same portion of the specification discusses identified mutations of SEQ ID NO: 1 that are predicted to have a deleterious effect on the encoded protein product. Additionally, the specification, at, for example page 20 lines 9-13, page 20, line 23 through page 21, line 14, and Table 1, describes detecting missense, nonsense and frameshift mutations, thus providing support for the amendments to Claim 4.

Claim 5 has been amended to correct a self-evident typographical error.

Claims 41, 43 and 44 have been amended in light of Applicants' election of Group II and to clarify that the claimed invention involves detecting a mutation in SEQ ID NO: 1

Classification of Claims 43-46 as Nucleic Acid Composition Claims of Group I

Applicants note that the Examiner has classified Claims 43-46 as nucleic acid claims encompassed by the invention of Group I. Applicants respectfully point out that these claims are method claims drawn to detecting Lafora's Disease by detecting a mutation in the nucleic acid. Claims 43-46, as method claims, do not belong in Group I and Applicants respectfully request that they be examined with the claims of Group II.

Traversal of Restriction Requirement

- A. *Election to a single polymorphism is unduly restrictive and does not afford Applicants the protection for which they are entitled*

Applicants elect Group II (Claims 4-30, 40-41 and 43-46) drawn to methods of diagnosis for Lafora's Disease by detecting a mutation in the gene sequence. Applicants further elect the SNP resulting from a C to G change at nucleotide number 205 in the EPM2B gene sequence

comprising SEQ ID NO:1 for prosecution with traverse. It is respectfully requested that the Examiner reconsider and withdraw the requirement to elect a single SNP because such a requirement would unduly limit the claimed invention.

Applicants have discovered a novel gene, EPM2B. Applicants further discovered 21 distinct variations of the EPM2B gene. These variations are associated with Lafora's disease. Based upon the discovery that variations of the EPM2B gene are associated with Lafora's disease, Applicants submit that elected Group II encompasses these variations. For example, Applicants discovered a mutation resulting in a C to G transition at nucleotide position 205 in the EPM2B. Because the sequence of EPM2B has been specified and the disease, Lafora's disease, has been specified, the search parameters are well defined. A reasonable patentability search would include a search of the EPM2B gene and association of the gene with Lafora's disease. This search is not burdensome because Applicants are the first to associate EPM2B with Lafora's disease using a genomics based approach. A search of specific variants is not necessary if there is no prior art revealed that discloses an association between EPM2B and Lafora's disease. Thus, Applicants respectfully submit that this would not represent a serious search and examination burden to the Office and request reconsideration of the restriction requirement to include at least all of the variants of the EMP2B gene identified in the specification.

B. Applicants are entitled to the genus of all variants of the EPM2B gene

Applicants believe they are entitled to claim the entire genus of variations of the EPM2B gene that are associated with Lafora's disease. The variations described by Applicants define a class or genus of EPM2B gene variants. The mere fact that the members of the claimed genus are not identical in chemical structure does not negate the fact that all members of the genus have a substantial common core structure, namely, the nucleic acid sequence of EPM2B as set forth in SEQ ID NO: 1.

Applicants believe that the variations of the EPM2B gene that are associated with Lafora's disease define a class or genus of nucleic acids that should be examined together in the claims. If the Patent Office were to require the claims to be limited to a single variation of the EPM2B gene, Applicants would be forced to endure piecemeal examination of their invention. As such, multiple applications would have to be prosecuted to afford Applicants the patents needed to adequately protect their invention. In this case, at least 21 applications, and very likely

many more than 21 applications, would have to be filed for Applicants to gain patent protection for the method claims that the Examiner has placed in Group II.

In view of the above, Applicants respectfully request modification of the restriction requirement such that Group II includes all variants of EPM2B associated with Lafora's disease.

CONCLUSION

If the Examiner would like to discuss the Reply to Restriction Requirement and Preliminary Amendment, the Examiner is invited to call Applicants' undersigned Attorney.

Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 08-0380.

Respectfully submitted,

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